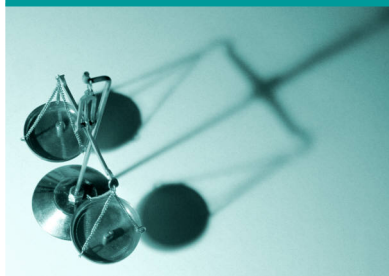
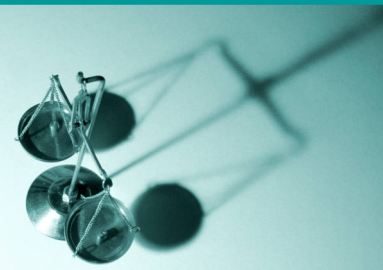


Update on Medicare Part D



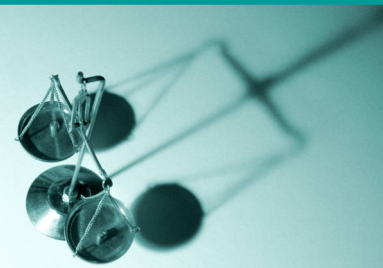
**NOPLG Seminar
Portland, Oregon
April 17 - 20, 2007**

Robert L. Roth, Esquire
Crowell & Moring LLP
1001 Pennsylvania Ave., NW
Washington, DC 20004-2595
Tel: 202-624-2870
Fax: 202-628-5116
rroth@crowell.com



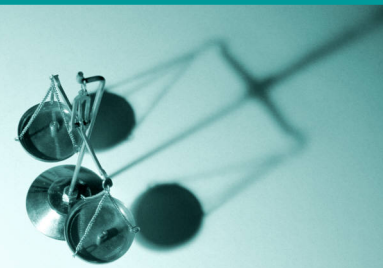
Update on Medicare Part D

- Nature of Part D Benefit
- How the Benefit is Delivered
- Price Negotiation



Update on Medicare Part D

- Scope of Benefit
- Alternative Benefit Structures
 - Basic
 - Enhanced



Update on Medicare Part D

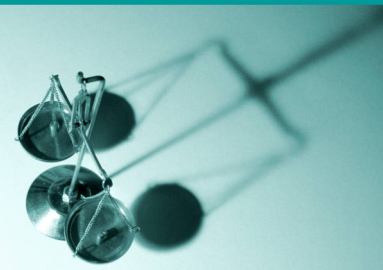
Access

- Network Pharmacies
- Out-of-Network Pharmacies
- Physician Offices
- Hospitals
- Long Term Care Facilities



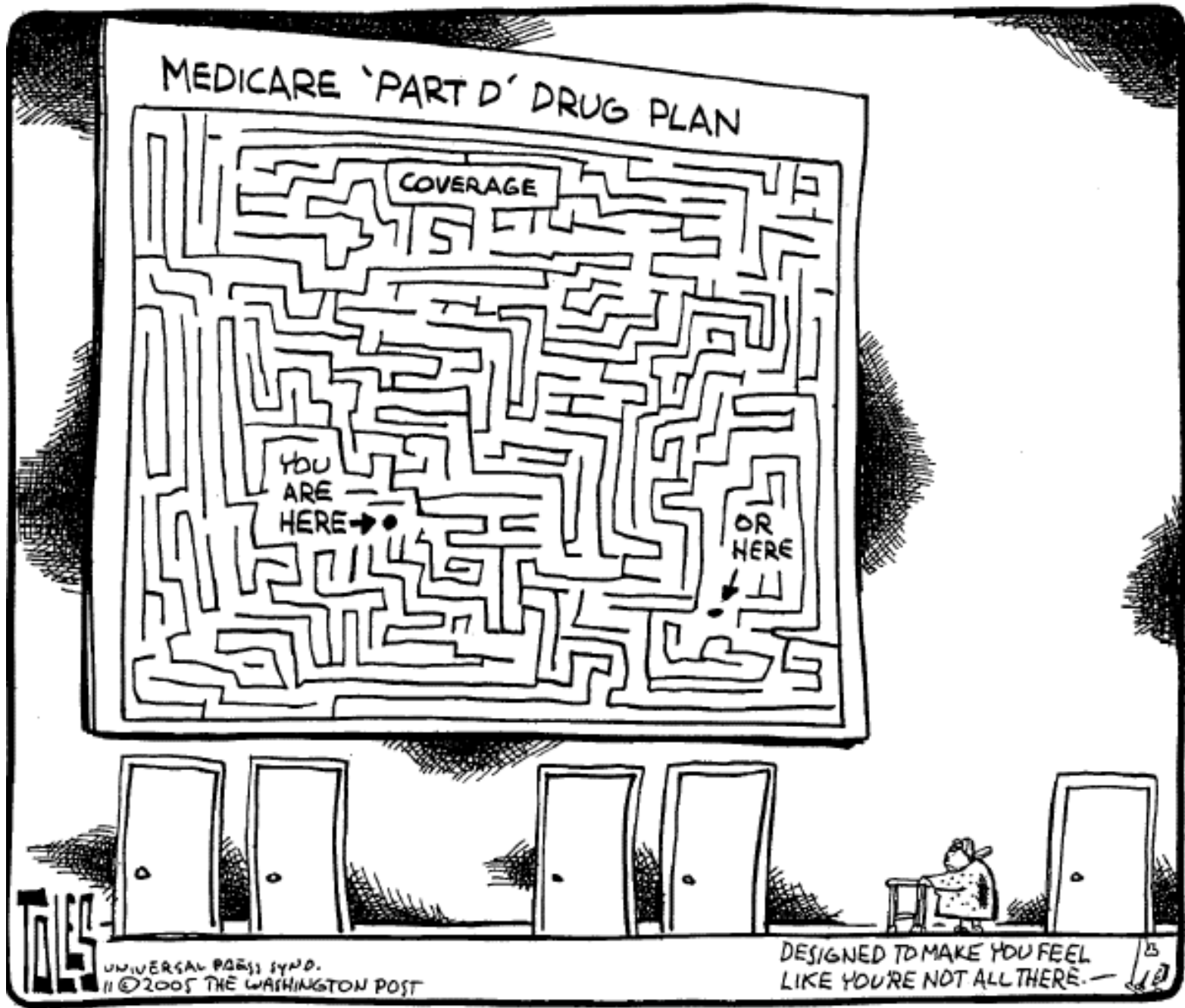
Update on Medicare Part D

- What Drugs are Covered
- What Drugs are Excluded
- Off-Label Uses
- Part B vs. Part D Coverage
- Formulary Issues



Update on Medicare Part D

- Part D and Long Term Care Facilities
- Part D and Hospitals



MEDICARE 'PART D' DRUG PLAN

COVERAGE

YOU ARE HERE → ●

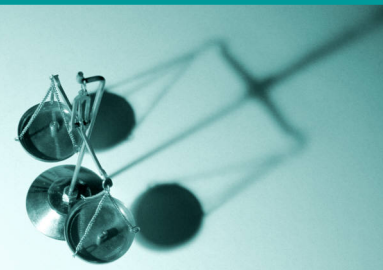
OR HERE
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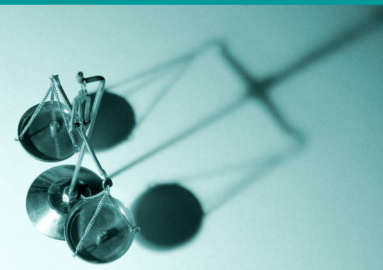
DESIGNED TO MAKE YOU FEEL
LIKE YOU'RE NOT ALL THERE.

13



Update on Medicare Part D

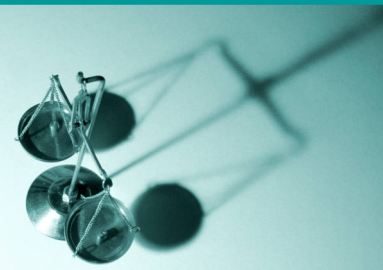
- Payments to Part D Plans
- TrOOP
- COB
 - MSP
 - TPL



Update on Medicare Part D

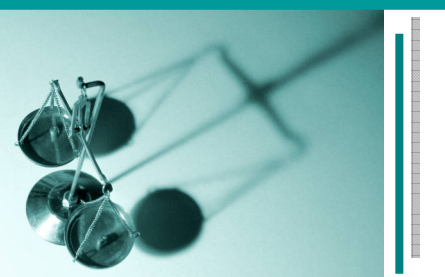
Appeals, Exceptions, Grievances

- Subject Areas
- Processes



Update on Medicare Part D

- Reconciliation and Audits
- Certifications
- False Claims Act Liability Exposure



Update on Medicare Part D

OIG Work Plan (<http://oig.hhs.gov/publications/workplan.html>)

OIG Advisory Opinions

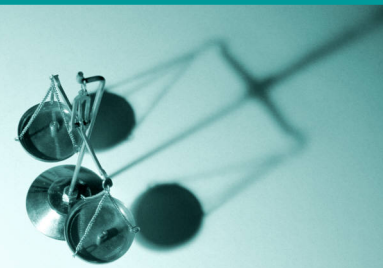
(<http://oig.hhs.gov/fraud/advisoryopinions.html>)

OIG Compliance Guidance

(<http://oig.hhs.gov/fraud/complianceguidance.html>)

**Chapter Nine of the CMS Prescription Drug
Plan Manual “Fraud, Waste, and Abuse”**

(http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf)



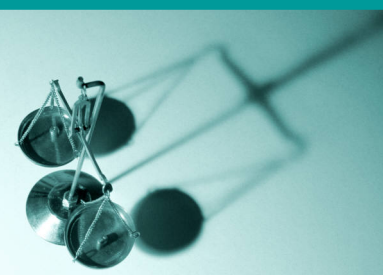
Update on Medicare Part D

1. Must have written policies and procedures and a code of conduct
2. Must have a compliance officer
3. Must have a compliance committee
4. Must provide training and education to employees, subcontractors and agents.
5. Must have communication between the compliance officer and employees, contractors, agents, directors, and members of the compliance committee.
6. Must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to potential violations.
7. Must have procedures for internal monitoring and auditing
8. Must have a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse.



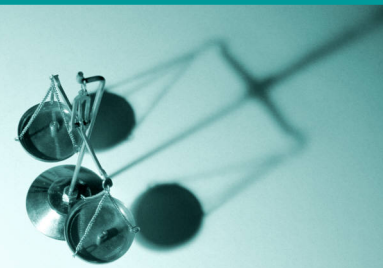
Update on Medicare Part D

- Over 30 topics covered
 - Most will be new for plans
 - Some will prove difficult to draft and implement
 - Associated training
 - Audience varies, but is broad
- Operational
 - Pricing decisions
 - P&T Committee decisions
 - Identifying overpayments and process to repay
 - Considerations of corrective action
- HR
 - OIG/GSA exclusion and debarment lists
 - Employment applications
 - Employee discipline
 - Outside employment



Update on Medicare Part D

- There is recognition in Chapter 9 that Part D plans are not law enforcement agencies,
- **BUT . . .**
 - The plan *must* conduct a timely, *reasonable* inquiry into any conduct where “evidence suggests” there has been misconduct related to payment or delivery of prescription drug items or services under the Part D contract.



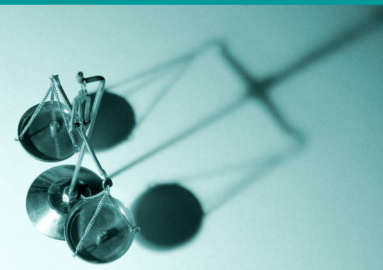
Update on Medicare Part D

- While the regulations make it clear that self-reporting of potential fraud is voluntary, CMS believes that self-reporting of fraud, waste and abuse is a *critical* element to an effective program to control fraud, waste and abuse.
- Hence, CMS states that sponsors “should” refer any possible infractions that they have identified to CMS or the appropriate MEDIC for further investigation *within 60 days of any determination that a violation might have occurred.*



Update on Medicare Part D

- In theory, at least, a compliance program – especially if fraud was detected through the compliance program – can help persuade the government that the plan did not act knowingly, willfully, or with reckless disregard if compliance issues are uncovered.
- Likewise, poor compliance programs or inadequate auditing or monitoring might undermine a defense that problems are the result of innocent mistakes or system errors.
- BUT . . . Overall, Chapter 9 is very ambitious in scope – possibly too ambitious for some plans.



Update on Medicare Part D

Questions & Answers